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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,710	07/03/2001	Albert Chin	1001.1468101	2449

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EXAMINER	
SHIPSIDES, GEOFFREY P	

ART UNIT	PAPER NUMBER
1732	7

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)
	09/898,710	CHIN ET AL.
	Examiner	Art Unit
	Geoffrey P. Shipsides	1732

-- The MAILING DATE of this communication appears on th cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *16-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Claims 16-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,404,203 (Donald).

Donald teaches a method for extruding a bi-helically oriented thermoplastic tube (title). Donald teaches the use of an extruder that has an extrusion head (Figure 1) and the extrusion of an elongated thermoplastic tubular member. Donald teaches the use of various polymers in the production of this thermoplastic tubular member including polyvinylchloride, polyethylene, and polypropylene (Column 3, lines 63-64). Donald teaches the cooling of the thermoplastic tube to below the heat plastifying temperature (and thus the solidification of the tubular member). Donald teaches the rotating of the mandrel and an affixed die (24) in opposite directions at a point directly after the material exits the main internal passageway (16) in order to impart molecular orienting

of the heat plastified thermoplastic material adjacent to the mandrel and the affixed die (Figures, Claim 1, Column 2, lines 22-48). This constitutes a teaching of rotating the elongated polymer member downstream of the extrusion head (internal passage) prior to solidification in order to impart molecular helical orientation to the elongated polymer member. The orientation is imparted while the material is in a heat plastified state (molten state) and this takes place in close proximity to the extrusion head. It is inherent in the process that the polymers used in this process would have a melting temperature and a glass transition temperature and it is further inherent that the orientation process would take place while the polymer used by Donald is at a temperature in this range.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,951,494 (Wang et al.) in view of U.S. Patent No. 3,404,203 (Donald).

Wang et al. teaches a process of forming a medical instrument, formed at least in part of elongated polymer members, which exhibits high torque fidelity after processing with tension, heat, and twisting (Abstract). Wang et al. teaches, "The polymer may be PET, Nylon, or PEBAX. The polymer may be oriented or heat set at a temperature substantially greater that sterilization temperature." (Column 1, lines 65-67) Wang et

al. further teaches, "The element may be in the form of a tube" (Column 2, line 3). Wang et al. teaches that the element may be a coextrusion of polymers or a coextrusion of different polymers. Wang et al. teaches, "The element may include polymer molecules oriented linearly, along the axis. The element may include polymer molecules oriented on helical paths oriented about the axis in opposite directions. The element may include a first polymer layer with polymer molecules oriented along helical paths extending in one direction about the axis and a second polymer layer with polymer molecules oriented along helical paths extending in the opposite direction about the axis." (Column 2, lines 6-17). Wang et al. teaches that the process to make this includes "stretching the member by the tensioning. The process may include placing the polymer member in tension and rotating one end of the polymer member while holding the other end rotationally stationary. The process may include simultaneously heating, twisting, and stretching." (Column 2, lines 23-28) Wang et al. teaches that the preformed polymer member may be in the form of a rod or tube and formed by extrusion (Column 7, lines 5-11). Wang et al. teaches that the polymer is typically heated to a temperature well above the glass transition temperature but well below the melting point, for example between 200-250 degrees F (Column 8, lines 54-57). Wang et al. teaches that the rotation and translation speeds can be varied to affect the torque fidelity (Column 9, lines 8-9). Wang et al. teaches that the rotation rates are in the range of about 100-200 rpm (Column 9, lines 16-17).

With regard to claims 1-4, Wang et al. does not teach the rotation of the preformed member as it exits an extruder head. Wang et al. does not specifically teach

the extrusion process of the preformed member, Wang et al. simply teaches a manipulation of a preformed (possibly extruded tubular) member in order to impart orientation to the member.

Donald, however, teaches a method for extruding a bi-helically oriented thermoplastic tube (title). Donald teaches the use of an extruder that has an extrusion head (Figure 1) and the extrusion of an elongated thermoplastic tubular member. Donald teaches the use of various polymers in the production of this thermoplastic tubular member including polyvinylchloride, polyethylene, and polypropylene (Column 3, lines 63-64). Donald teaches the cooling of the thermoplastic tube to below the heat plastifying temperature (and thus the solidification of the tubular member). Donald teaches the rotating of the mandrel and an affixed die (24) in opposite directions at a point directly after the material exits the main internal passageway (16) in order to impart molecular orienting of the heat plastified thermoplastic material adjacent to the mandrel and the affixed die (Figures, Claim 1, Column 2, lines 22-48). This constitutes a teaching of rotating the elongated polymer member downstream of the extrusion head (internal passage) prior to solidification in order to impart molecular helical orientation to the elongated polymer member. The orientation is imparted while the material is in a heat-plastified state (molten state) and this takes place in close proximity to the extrusion head. It is intrinsic in the process of Donald that the polymers used in this process would have a melting temperature and a glass transition temperature and it is further inherent that the orientation process would take place while the polymer used by Donald is at a temperature in this range.

It would have been obvious to one having ordinary skill in the art at the time of invention to produce the oriented tubular member of Wang et al. by the process of Donald in order to reduce the number of steps involved in the process of producing the product of Wang et al. by simply extruding the polymer and orienting it as it leaves the extruder. One having ordinary skill in the art at the time of invention would have further been motivated to use the process of Donald to make the product of Wang et al. because it would save energy by removing the need to reheat the member to above the glass transition temperature.

With regard to claims 5 and 6, although Wang et al. teaches a lower rotational speed, it is clear from the teachings of Wang et al. that the rotational speeds effect the orientation (and hence the strength) of the members, and it would have been obvious to one having ordinary skill in the art to determine the optimal amount of rotational speed required in order to produce the best tube when producing the tube as taught by Wang et al. by the process of Donald. Further, Donald does not teach a specific rotation rate, nor does Donald teach a specific extrusion rate. It is, however, well known in the art of extrusion to mold at various extrusion rates and that the faster the extrusion the more efficient the extrusion process, but that with very fast extrusion process that quality may suffer. It is also clear from the teachings of Donald and Wang et al. that the rotation rate would affect the degree of orientation of the polymer and that greater orientation increases the strength of the polymeric member. It is clear from Donald and Wang et al. that the rotation rate is a result effective variable that would depend upon the desired amount of orientation in the produced member, the temperature and material of the

extruded member, the extrusion rate of the member, etc. It would have been obvious to one having ordinary skill in the art at the time of invention to determine the optimal extrusion rate and the optimal rotation rate through routine experimentation as these are obvious result effective variables from the teachings of Donald and Wang et al. in order to optimize the process of Donald to produce high quality oriented members with the desired orientation at the fastest speed possible.

With regard to claim 7, Wang et al. teaches that the rotation and translation speeds can be varied to affect the torque fidelity (Column 9, lines 8-9). It would have been obvious to one having ordinary skill in the art at the time of invention to vary the rotational rate in the process as taught by Donald in order to affect the torque fidelity in the finished product as is taught by Wang et al.

With regard to claims 8-10, Wang et al. teaches the use of members formed of two different coextruded polymers. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the process of Donald to twist after the coextrusion of two different polymers as is taught by Wang et al. in order to produce a product as is taught by Wang et al. by the process as taught by Donald, thus saving process steps, time, and heat energy. Further, Wang teaches the orientation of members with two different layers and members that change from one material to another. It is well known in the art to coextrude intermittently to get a part that changes from one material to another or continuously to produce a layered part. It would have been further obvious to one having ordinary skill in the art at the time of invention to coextrude the member by either of these two well-known methods of coextruding in

order to produce the type of articles taught by Wang et al., depending on which type of article as taught by Wang et al. is desired.

With regard to claims 11-13, Donald teaches the extrusion of the tubular member on to a rotating core member and then the removal of the extrudate from the core member.

With regard to claims 14 and 15, Wang et al. teaches a product made of two different polymers where the different polymers have different orientations. It would have been obvious to one having ordinary skill in the art at the time of invention that in order to impart two different orientations, that a first inner member of one orientation would have to be made by the process of Donald, then passed back through the process of Donald and used as the core member in order to impart a second orientation to the second layer.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 2,616,126 (Merck et al.), U.S. Patent No. 3,891,374 (Ninomiya et al.), U.S. Patent No. 5,156,785 (Zdrahala), U.S. Patent No. 5,248,305 (Zdrahala), U.S. Patent No. 5,882,741 (Rubin et al.), and U.S. Patent No. 6,436,056 (Wang et al.) are cited as art of interest to show the current state of the art at the time of invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Geoffrey P. Shipsides whose telephone number is 703-306-0311. The examiner can normally be reached on Monday - Friday 9 AM till 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan H Silbaugh can be reached on 703-308-3829. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Geoffrey P. Shipsides/gps
December 15, 2002

Jan H Silbaugh

JAN H. SILBAUGH
SUPERVISORY PATENT EXAMINER
ART UNIT 1732

12/15/02